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EXAMINER	
PORTER, RACHEL L	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,682	MAYAUD, CHRISTIAN	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 11/9/05. Claims 70 and 72-74 have been cancelled. Claims 75-96 have been newly added and are presently pending.

Response to Amendment

2. The declarations filed on 11/9/05 under 37 CFR 1.131 has been considered but is ineffective to overcome the Schrier (USPN 5,833,599) reference.

(A) The declaration of Christian Mayaud states in sections 3-8 that Applicant made a confidential presentation to a third party regarding the invention "Physicians' Online." Applicant refers to exhibits A-G as demonstrating the "Physician's Online" product.

The affidavit (sections 1-9, 11, and 13) and exhibits (A-I) are insufficient because the affidavit and exhibits are not commensurate in scope with the claimed invention. In particular, it is respectfully submitted that the affidavit broadly discusses *system* features of claimed features in "sister application" 09/941,681. However, the affidavit fails to tie the exhibits A-I to the features of the current claimed invention. In particular, the Examiner understands that the Applicant is currently seeking patent protection for "an electronic prescription." The structure and full functionality of the "electronic prescription" itself *as distinct from the system components*, is not clear in the claim language (as will be discussed in the 112, 2nd rejection included in the present office action) and therefore conception and reduction to practice of the claimed features of the electronic prescription is not evidenced by the submitted affidavits. the affidavit does

not demonstrate where the features, for example "a library of prescribed drug data..." and "drug formulary information..." of claim 71, are found in exhibits A-I. Appropriate clarification is requested.

(B) The declaration submitted by Ted W. Whitlock on 11/9/05 has also been considered. However, the declaration does not attest to facts relating to the instant application 09/681,682. Instead, many of the statements focus on agreements reached between Mr. Whitlock and the Examiner of another Examiner Rimmell regarding the merits of a "sister application," 09/941,681. These statements are not binding in the present application since the present application claims distinct subject matter.

Mr. Whitlock's statements fail to provide a connection between the Mayaud declarations presented and the currently claimed subject matter drawn toward the "electronic prescription.

Response to Arguments

3. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Additional arguments and explanations regarding the 112, 2nd paragraph rejection, and the 101 rejections have been included in the new grounds of rejection.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 75-96 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Exemplary claim 75 recites " an electronic prescription comprising..." The recited prescription is considered to be non-statutory.

First of all, it is not entirely clear which statutory class of invention the recited "electronic prescription" encompasses. The recited (electronic) prescription per se, is considered to be non-functional descriptive material. Certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or *compilations of facts or data*, without any functional interrelationship is not a process, machine, manufacture or composition of matter.

It is noted that the current language of claim 75 recites that the electronic prescription is stored on a computer-readable medium. However, when nonfunctional descriptive material is recorded on some computer-readable medium, it is still not statutory since no requisite functionality is present to satisfy the practical application requirement of 101. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. *In re Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) MPEP § 2106 provides further guidance on 35 U.S.C 101 and descriptive material.

In light of the above, it is respectfully submitted that the claimed invention, does not have a tangible result, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

A similar analysis may be applied to claims 76-96, which are also rejected.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 75-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 75, it is unclear whether the applicant intends to claim the prescription or the prescription creation system. The current claim language suggests that the Applicant is attempting to claim a product-by-process or product-by-system (prescription by prescription creation system). However, it should be noted that only the components from the system which affect the resultant prescription will be given patentable weight and have art applied accordingly.

It is also unclear which components are included in the recited "electronic prescription" and/or how this "prescription" is embodied. In other words, it is unclear if applicant intends to recite data stored in some storage medium (e.g. a database) or if the prescription is software, which is actually capable of causing functional changes when executed.

In *IPXL Holdings, L.L.C. v Amazon.Com, Inc.* (CAFC, 05-1009, -1487, 11/21/2005), the court held a claim covering two statutory classes to be properly rejected under 112,2nd paragraph:

> Whether a single claim covering both an apparatus and a method of use of that apparatus is invalid is an issue of first impression in this court. The Board of Patent Appeals and Interferences ("Board") of the PTO, however, has made it clear that reciting both an apparatus and a method of using that apparatus renders a claim indefinite under section 112, paragraph 2. Ex parte Lyell, 17 USPQ2d 1548 (BPAI 1990). As the Board noted in Lyell, "the statutory class of invention is important in determining patentability and infringement." Id. at 1550 (citing In re Kuehl, 475 F.2d 658, 665 (CCPA 1973); Rubber Co. v. Goodyear, 76 U.S. 788, 796 (1870)). The Board correctly surmised that, as a result of the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus. Id. Thus, such a claim "is not sufficiently precise to provide competitors with an accurate determination of the 'metes and bounds' of protection involved" and is "ambiguous and properly rejected" under section 112, paragraph 2. Id. at 1550-51. This rule is well recognized and has been incorporated into the PTO's Manual of Patent Examination Procedure. § 2173.05(p)(II) (1999) ("A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph."); see also Robert C. Faber, Landis on Mechanics of Patent Claim Drafting § 60A (2001) ("Never mix claim types to different classes of invention in a single claim.").

As such, the Examiner is interpreting the claims to mean that the Applicant is claiming the prescription, *not* the prescription creation system. Therefore, limitations which further define the prescription creation system but do not appear in the resultant prescription (i.e. captured in the prescription) will not receive patentable weight. (See MPEP 2113)

7. Claim 84 recites the limitation "said drugs in said drug list" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 75 does not recite "a drug list" per se, but makes reference to "at least on drug chose from a list provided by an electronic prescription creation system" and also refers to "a library of prescribable drugs." It is unclear to the examiner components listed in claim 75 is the recited "drug list." For the purpose of examination, the Examiner will interpret this limitation to mean the library of the drugs stored by the system

As per claim 93, it is unclear is intended by the phrase "the system providing all said output options." The phrase "all said output options" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "all"), particularly because no output options are listed in the current claim, thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 76-96 also inherit the deficiencies of claim 75 through dependency and are also rejected.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 75-85,87, and 89-95 are rejected under 35 U.S.C. 102(e) as being anticipated by Schrier (USPN 5,833,599).

[Claim 75] Schrier discloses an electronic prescription, comprising:

(A) a patient identifier; (Figure 11; col. 13, lines 38-52; col. 14, lines 48-64)

(B) at least one prescribed drug chosen from a list provided by an electronic prescription creation system, said list being provided based on a patient condition; ; (Figure 11; col. 13, lines 38-52; col. 14, lines 48-64)

(C) at least one drug quantifier for the prescribed drug; (Figure 11; col. 14, lines 15-20) said electronic prescription created by a electronic prescription creation system including a program stored on a computer-readable medium, said electronic prescription additionally being stored in a computer-readable medium (Figure 1; col. 4, lines 24-36; col. 5, lines 11-31)

- said electronic prescription creation system being accessible by a prescriber to create said electronic prescription for prescribing a drug to treat a condition exhibited by a patient at a point-of-care and (Figure 11—inpatient order, i.e. at a point of care)
- said created electronic prescription being usable by a pharmacist to dispense the prescribed drug or drugs; (col. 13, lines 17-23: orders/ prescriptions directed to pharmacist.
- whereby said electronic prescription further comprises said patient condition data; (col. 13, lines 6-10)

The remaining limitations are drawn to the various aspects prescription creation system, not electronic prescription itself. As such, these limitations will not be given patentable weight and will not distinguish the claimed prescription over the prior art of record.

[Claims 76-79] Schrier discloses a system for generating prescriptions electronically, in which the user (i.e. prescriber) may set personal preferences and decide how to customize the prescribing options (col. 13, lines 62-col.14, line 26). The system further includes patient history records for display, which list previously prescribed medications of the patient(s) and provide information on the patient's condition (Figures 1 and 11; col. 13, lines 6-10). However, these limitations are drawn to the prescription creation system, not the prescription. As such, these limitations will not be given patentable weight and will not distinguish the claimed invention over the prior art of record.

[Claims 80-81] Schrier teaches a system for generating electronic prescription electronic prescriptions, wherein said system further includes a data-retrieval subsystem, said data retrieval subsystem being connectable to access at least one data retrieval network to retrieve source prescribing information and patient-related data (including information on allergies or drug interactions) to the point-of-care from at least one remote source database. (Figure 1 and 11; col. 4, lines 24-49; col. 5, lines 5-32) However, these limitations are drawn to the prescription creation system, not the

prescription. As such, these limitations will not be given patentable weight and will not distinguish the claimed invention over the prior art of record.

[Claims 82-83] Schrier discloses a system for generating an electronic prescription according wherein said patient history record is a contemporaneous record dynamically assembled from multiple source record elements retrieved from multiple remote databases and which further comprises a user interface device a user interface device configured for networked digital communication with a host computer facility. (Figure 1,col. 6, lines 4-32; col. 13, lines 38-52) Moreover, these limitations described in the present claims are drawn to the prescription creation system, not the prescription. As such, these limitations will not be given patentable weight and will not distinguish the claimed invention over the prior art of record.

[Claim 84] Schrier discloses a system wherein the drug list in the system library may be classified and selectable according a patient conditions (Figures 1, 9-10)

[Claim 85] Schrier discloses a system for generation of an electronic prescription according to claim 75. Schrier further discloses that the system includes a display to provide information on condition driven and formulary-driven drug recommendations (col. 14, lines 6-20) The remaining limitations are drawn to the various aspects prescription creation system, not electronic prescription itself. As such, these limitations

will not be given patentable weight and will not distinguish the claimed prescription over the prior art of record.

[Claim 87] Schrier discloses an electronic prescription according to claim 75 including information regarding prescribability of a drug pursuant to formulary guidelines, said information being formulary-qualified according to said patient condition. (Figure 11;col. 14, lines 15-20: e.g. no generic)

[Claim 89] Schrier discloses an electronic prescription according to claim 75, said system including a prescription expiration routine including dosing, amount and expiration drug quantifiers and including system calculation of a relationship between said drug quantifiers. (Figure 11; col. 6, lines 12-col. 7, lines 46)

[Claim 90] Schrier discloses a system for generating electronic prescription according to claim 75 said system including organization-generated source data retrievable for display in said prescription-creation system from at least one remote database, an organization directed data-access control subsystem including data-access control specification means enabling an organization to authorize selective third party access to said organization generated source data and including data access control means whereby only an authorized third party can access said organization-generated source data. (Figures 1, 11; col. 13, lines 24-52: e.g. The hospital system includes information gathered from patients and provides restricted access to users, including physicians

and pharmacists) Moreover, these limitations described in the present claim are drawn to the prescription creation system, not the prescription. As such, these limitations will not be given patentable weight and will not distinguish the claimed invention over the prior art of record.

[Claim 91] Schrier discloses an electronic prescription according to claim 75 wherein said condition list includes at least five conditions and said drug list includes at least five drugs. (Figures 9-10, 12-13;col. 8, lines 36-48;col. 11, lines 32-47)

[Claim 92] Schrier discloses an electronic prescription according to claim 75 wherein said drug information includes associated condition information and dosage information for at least about fifty percent of all prescribable FDA-approved drugs. (col. 11, lines 32-47)

[Claim 93] Schrier discloses an electronic prescription generating system, said system including output means to output a newly created electronic prescription additionally to local storage to remote storage or to remote file transfer as an electronic prescription, the system providing said output options. (Figure 11, col. 13, lines 17-23;col. 14, line 65-col. 15, line 5)

[Claim 94] Schrier discloses an electronic prescription according to claim 75 said system including means for transmitting said electronic prescription across a network for fulfillment by a specified pharmacy. (col. 13, lines 17-23)

[Claim 95] Schrier discloses an electronic prescription according to claim 93 including a printed dosage schedule output for said patient. (col. 13, lines 12-16—printout of patient order with patient information/prescription)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 86, 88, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier.

[Claim 86] Schrier discloses a system for generating an electronic prescription including means to access remote source databases containing said drug formulary information, whereby relevant patient formulary drugs are indicated to said user on screen. (Figure 1,11; col. lines14, 6-20). Schrier does not expressly disclose that the formulary drug information is provided from the patients pharmacy benefit's company. At the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to provide benefits information (i.e. insurance benefits, eligibility, pricing

information) directly from the insurer or benefits provider. One would have been motivated to include this feature to insure that the benefits data was as accurate as possible.

Moreover, these limitations described in the present claim are drawn to the prescription creation system, not the prescription. As such, these limitations will not distinguish the claimed invention over the prior art of record.

[Claim 88] Schrier discloses system for generating electronic prescriptions wherein users must login to access the system, (col. 13, lines 24-52), but does not expressly disclose that the system maintains an audit trail of users accessing the system. However, at the time of the applicant's invention, audit trails were old and well known in the art to track system use. At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schrier to include a auditor log feature to track users accessing the system. One would have been motivated to include this feature to encourage patient privacy and prevent prescription fraud.

[Claim 96] Schrier discloses a system for generating an electronic prescription wherein the system further includes: a drug formulary display device identifying at least one of said displayed multiple drugs as a patient's drug formulary preference for treatment of said condition, to enable selection by said prescriber of a benefit plan recommended drug, whereby the patient's drug formulary preference for treatment of said condition is

system-presented to the prescriber prior to completion of the prescription. (Figure 11, col. 14, lines 6-20). Schrier does not expressly disclose that the formulary drug information is provided from the patients pharmacy benefit's company. At the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to provide benefits information (i.e. insurance benefits, eligibility, pricing information) directly from the insurer or benefits provider. One would have been motivated to include this feature to insure that the benefits data was as accurate as possible.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP

RP

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